Vaginal Yeast Test

A rapid test for the qualitative detection of Candida antigens in cervical secretion.

Instruction Manual

Test kit for 20 tests individually pouched
(Catalog No. 41013)

For Professional Use **ONLY**
Store at 2-30°C. ***Do Not Freeze***

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Intended Use

The ***Vaginal Yeast Test*** is a rapid lateral flow-based assay for qualitative detection of *Candida* antigens in cervical secretion sampled by a swab.
For *in vitro* diagnostic use only.

Introduction

Vulvovaginal candidiasis (VVC) is thought to be one of the most common causes of vaginal symptoms. Approximately, 75% of women will be diagnosed with *Candida* at least once during their lifetime. 40-50% of them will suffer recurrent infections and 5% are estimated to develop chronic Candidiasis. Candidiasis is more commonly misdiagnosed than other vaginal infections (trichomonas and bacterial vaginosis). Symptoms of VVC which include: acute itching, vaginal soreness, irritation, rash on the outer lips of the vagina and genital burning that may increase during urination, are non specific. Clinicians should keep in mind that a broad variety of infectious and noninfectious diseases can cause a similar array of symptoms. To obtain an accurate diagnosis, a thorough evaluation is necessary. In women who complain of vaginal symptoms, the standard tests, which should be performed, consist of a vaginal pH measurement, saline and 10% potassium hydroxide microscopy. Microscopy is the mainstay in the diagnosis of VVC, yet studies show that, in academic settings, microscopy has a sensitivity of at best 50% and thus will miss a substantial percentage of women with symptomatic VVC. To increase the accuracy of diagnosis, yeast cultures have been advocated by some experts as an adjunctive diagnostic test, but these cultures are expensive and underutilized, and they have the further disadvantage that it may take up to a week to get a positive result. Inaccurate diagnosis of Candidiasis may delay treatment and cause more serious lower genital tract diseases. The ***Vaginal Yeast Test*** *is* a point-of-care test for qualitative detection of *Candida* cervical secretion swabs within 10-20 minutes. It is an important advance in improving the diagnosis of women with VVC.

Principle of the test

The ***Vaginal Yeast Test*** is an immunoassay in which *Candida* antigens interact during flow along the test strip with anti-*Candida* specific antibodies conjugated to blue latex particles used as detector. The outcome complex binds during the continuation of the flow to anti-*Candida* specific antibodies that are immobilized in the detection zone, to create a blue line. The presence of a blue line at the test line position indicates a positive result. The conjugated latex particles interact downstream the test line with other specific antibodies to create the control line. The presence of a blue line at the control line position indicates proper function of the test.

Reagents

The test device contains dried antibodies and latex particles applied on the test strip, and ready-to-use extraction/running buffer sealed in the upper part of the device.

Precautions

- For *in vitro* diagnostic use only. Do not use after expiration date.
- The test device should remain in the sealed pouch until use.
- Do not use test if pouch is damaged.
- Do not eat, drink or smoke in the area where the specimens or device are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Use only **sterile** swabs included in kit to obtain endocervical specimens.

Storage and Stability

Store as packaged in the sealed pouch at room temperature (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Materials

Materials Provided
- Test devices
- Sterile swabs
- Package insert

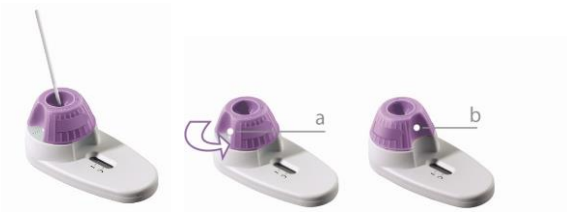
Materials required but not supplied
- Watch

Directions for Use

1. Remove the device from the sealed pouch and place it on a flat horizontal surface.
2. Hold the device stable with one hand. Carefully remove the aluminum cover of the purple cap with the other hand. **Note! The purple cap contains liquid**
3. Remove swab from the wrapper.
4. Insert the swab one inch (2cm) inside the vagina, and rotate **for 20sec**. Pull the swab out carefully!

5. Rotate the swab in the liquid placed in the purple cap, **for 20sec**.

6. Pull out the swab carefully while squeezing it against the inner wall of the purple cap. **Discard the swab.**
7. Hold the device stable with one hand. **Turn the purple cap counterclockwise until it stops (b), and then turn it back to starting point (a).**
8. Repeat step no.7 two more times. **In the final position the notches on the purple cap and the white base must be aligned (b).**



9. **Read results after 10 minutes**. A blue line should appear at the control (C) mark. In case of positive results, an additional blue line should appear at the test (T) mark. **In case of negative or unclear result read again after 10 more minutes.**

Interpretation of Results

1. **Positive** - Appearance of both lines-Detection of yeast infection.

NOTE: The intensity of the color in the test line region (T) should be considered positive even if the colored line is faint

2. **Negative** - Appearance of only the control line (C). No detection of yeast infection.

3. **INVALID: Control line fails to appear.** Insufficient sample volume or incorrect procedural techniques are the most likely reasons for absence of control line. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit and contact your local distributor.

Quality Control

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Limitations

1. The ***Vaginal Yeast Test*** is for *in vitro* diagnostic use only.
2. Being a qualitative test, no conclusions of a quantitative nature may be derived following its results.
3. The ***Vaginal Yeast Test*** will indicate the presence of *Candida* antigens in cervical secretion specimens only, while performance with other specimens has not been assessed.
4. Therapeutic failure or success cannot be determined based on the test results.
5. Excessive blood on the swab may cause false positive results
6. Do not use this test within 7 days after taking medications for vaginal infections.
7. Do not use this test within 24 hours after using crème, gel, foam, douching solutions or any other vaginal product

Performance Characteristics

Sensitivity and Specificity
The ***Vaginal Yeast Test*** has been evaluated with specimens obtained from symptomatic patients. Culture was used as the reference method. Specimens were considered positive if the culture indicated a positive result. Specimens were considered negative if culture indicated a negative result. The results show that the ***Vaginal Yeast Test*** has a high sensitivity and specificity relative to culture results.

Vaginal Yeast Test	**Culture**		
	Positive	**Negative**	**Total**
POSITIVE	30	2	32
NEGATIVE	5	33	38
TOTAL	35	35	70

Sensitivity: 30/(30+5) = 86%
Specificity: 33/(33+2) = 94%
Accuracy: (33+30)/70 = 90%

Cross-Reactivity
The antibody used in the ***Vaginal Yeast Test*** detects the most abundant *Candida* species.
Cross reactivity with the following major bacterial vaginosis strains has been studied using 10^7 Colony Forming Units (CFU)/mL.:
Gardnerella vaginalis, Mobiluncus curtissi, Prevotella bivia
Streptococcus A, Streptococcus B
None of the above-tested strains was detected by the ***Vaginal Yeast Test***

Bibliography

1. Egan M.E., Lipski M.S., Diagnosis of Vaginitis, American Family Physician, September 2000, pp 1-14.
2. Sobel J.K. et. Al., Volvovaginal candidiasis: Epidemiologic, diagnostic and therapeutic considerations. American Journal of Obstetrics and Gynecology V178(2), 1998.

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